PTO/PCT Rec'd 23 NOV 1999
PCT/US98/10864
09/424440

# GLASS CORE GUIDEWIRE COMPATIBLE WITH MAGNETIC RESONANCE HAVING REINFORCING FIBERS

## BACKGROUND AND SUMMARY OF THE INVENTION

1. Technical Background:

The present invention relates generally to intravascular medical devices, and more particularly, to a medical guidewire having reinforcing fibers for use with magnetic resonance systems. Such guidewires may be used in medical procedures for both diagnostic and interventional purposes.

2. Discussion:

Guidewires are used in a wide variety of medical procedures, most often in conjunction with one or more other medical devices, including catheters. Such a catheter may be any of various types, such as angiography or angioplasty, but should in any event have a tubular lumen or other guiding means through which the guidewire can be advanced or withdrawn.

Structurally, guidewires are often long, thin metal wires that generally taper from one diameter at a proximal end which remains outside the body of the patient, to a smaller diameter at the opposite distal end. Specifically, vascular guidewires are often more than five feet long and have a maximum outer diameter of approximately 0.035 inches. The diameter of the core wire is generally ground down precisely in a series of alternating tapering portions and constant diameter sections, to develop a selectively engineered flexibility profile along the length of the guidewire.

The guidewire distal tip is usually very flexible, both to avoid vascular trauma and so that it can be selectively bent and twisted to advance it along a desired vascular path. Guidewires are designed to resist this twisting force or torsion, so that as the guidewire proximal end is twisted or rotated, the distal tip tends to rotate through about the same angle. In addition, a floppy spring is often affixed to the extreme distal tip of the guidewire for flexibility.

A good example of a current guidewire is described in the commonly assigned United States Patent number 4,846,186, issued to Box et al. on July 11, 1989, which is incorporated in this disclosure by reference. The Box patent shows a guidewire suitable for both diagnostic and therapeutic or interventional procedures, having a Teflon coating from the proximal end along a majority of its length. The core wire tapers in steps to a distal portion that is flattened and surrounded by a flexible spring, which is brazed to the extreme distal end of the core wire to form a rounded tip.

As the body of the patient is of course opaque, physicians commonly use fluoroscopy or X-ray video cameras to track the position of the guidewire and to construct real-time images of the patient's vasculature. The visibility and brightness of selected portions of the guidewire is a relatively important feature, as described in the commonly assigned United States Patent number 5,259,393, issued to Corso, Jr. et al. on November 9, 1993, and United States Patent number 5,267,574, issued to Viera et al. on December 7, 1993. Both of these patents are incorporated in this disclosure by reference. In the Corso patent, the flexible spring at the guidewire distal tip is arranged to selectively control its brightness on an X-ray fluoroscope, or radiopacity. Likewise, the Viera patent discloses a plastic sleeve shrunk around an intermediate section of the guidewire, and several radiopaque marker bands.

In contrast to fluoroscopy, another method of visualizing the patient is magnetic resonance imaging, referred to as MRI. Other medical fields, such as neurology, often use procedures which are performed under MRI instead of X-ray fluoroscopy. Accordingly, it is also desirable to image the anatomy and to track the position of intravascular devices, including catheters and guidewires, using magnetic resonance (MR) systems.

For these applications, it is desirable to make guidewires usable and compatible with MRI techniques. However, a metal guidewire may be too visible under MR, brightly washing out the screen and obscuring important features. This halo phenomenon is called an "artifact," and renders the image useless. Another issue with the use of a metal guidewire under MR is the induction of eddy currents in the metal, caused by distortion of the magnetic field. These eddy currents can generate heat and may increase the local temperature of the surrounding tissue and body fluids, thus possibly damaging the tissue or causing the blood to coagulate.

It is an object of the present invention to provide a guidewire having the desired physical features, including torsion and flexibility, while also avoiding the creation of undesirable artifacts in the MR image or the generation of heat.

The present invention provides a guidewire compatible for use with magnetic resonance systems, made from a non-metallic material with a high specific electric impedance. Accordingly, this material will resist any electrical eddy currents in the guidewire from being generated by variations in the high-frequency field. An acceptable class of materials is glass, which are all electrical insulators. A guidewire having a major portion constructed of a glass material should therefore have the advantages of not disturbing the MR field and images, as well as resisting the generation of heat.

These and various other objects, advantages and features of the invention will become apparent from the following description and claims, when considered in conjunction with the appended drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a guidewire for use with magnetic resonance systems, arranged according to the present invention;

Figure 2 is a cross-sectional view of an intermediate portion of the guidewire of Figure 1;

Figure 3 is a cross-sectional view of a proximal end portion of the guidewire of Figure 1;

Figure 4 is a perspective view of a guidewire for use with magnetic resonance systems, arranged according the present invention;

Figures 5-7 are cross-sectional views of a portion of various guidewires arranged according to certain embodiments of the present invention;

Figure 8 is a perspective view of a guidewire for use with magnetic resonance systems, illustrating the reinforcing fibers of the present invention;

Figure 9 is a cross-sectional view of an intermediate portion of the guidewire of Figure 8;

Figure 10 is a cross-sectional view of a proximal end portion of the guidewire of Figure 8; and

Figures 11-13 are side elevation views of distal portions of guidewires arranged according to alternative embodiments of the present invention.

## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The following description of the preferred embodiments of the present invention is merely illustrative in nature, and as such it does not limit in any way the present invention, its application, or uses. Numerous modifications may be made by those skilled in the art without departing from the true spirit and scope of the invention.

Referring to Figure 1, a perspective view of a stent according to a preferred embodiment of the present invention is shown generally at 1. The medical guidewire 1 is intended for use in intravascular medical procedures involving the use of magnetic resonance systems, including both magnetic resonance imaging and magnetic resonance tracking of the guidewire's position within the body of the patient. Guidewire 1 is constructed of a basic body 2 and a distal tip portion 3. The distal tip of guidewire 1 includes several markers 4 embedded in the distal tip portion 3, which are more visible under MR than the remainder of the guidewire.

The proximal portion of the basic body 2 is illustrated in Figure 3, and incorporates a relatively long, thin core or glass body 5, which may be encased with a protective coating 6. The coated glass body 5 extends for substantially the length of the guidewire and is surrounded with a polymer sheath 7, which is adhered to the glass body 5 with a glue 8.

Markers 4 are visible under MR because they are susceptible to slightly distorting the uniformity of the magnetic resonance field, causing the magnetic field to become what is called "inhomogeneous." The material of the markers 4 is selected specifically for this property, and acceptable materials include Dysprosium Oxide ($Dy_2O_3$).

The glass body 5 is preferably made of a glass material having a high specific electric impedance, such as fiberglass, silica, or quartz.

The coating 6 adds strength to the glass core 5, in that the coating allows the glass core 5 to be bent through a sharper turn or more tortuous path without breaking. Indeed, it has been found that the coated glass core 5 may endure strain as high as 12%. A suitable material for the coating 6 has been found to be polyimide.

The outer polymer sheath 7 may be constructed from any of a variety of materials, including nylon. An additional advantage of the design of the present invention is that the polymer sheath 7 can maintain the physical integrity of the guidewire, even if the glass core 5 should unexpectedly break. Of course, the polymer sheath 7 may be provided with a lubricious or hydrophilic coating, as generally known in the art.

An intermediate portion of the guidewire is depicted in Figure 2, which focuses on a region near the transition at arrow II between the glass core proximal portion of the basic body, referred to as the "transition point."

The distal tip portion 3 of the guidewire 1 may be formed of a plastic, as shown in Figure 2, or of a metal as shown in Figures 8-13. The outer diameter of guidewire 1 preferably tapers to a smaller diameter toward the distal tip, as illustrated in Figures 8-13. The metal tip portion may be stainless steel or more preferably nickel titanium, or nitinol. Preferably, the length of the metal distal tip segment is substantially shorter than the wavelength of the magnetic resonance field in which the guidewire is used.

The glue 8 is preferably of a type that cures upon exposure to ultraviolet light. Accordingly, the polymer sheath 7 should be transparent, to allow the glue 8 to be exposed to the ultraviolet light after portions of the guidewire 1 are assembled as shown in Figures 1-3.

An embodiment of the present invention is depicted in Figures 4-7, in which a guidewire 11 has a proximal portion 12 and a distal tip portion 13. Guidewire 11 has a plastic sheath 16 in which a number of reinforcing fibers have been embedded. Sheath 16 may be shrunk around a bundle of fibers 17, or the sheath 16 may be braided with the reinforcing fibers. Alternatively, fibers 18 may be embedded in a polymer matrix 19. In addition, a multiplicity of short reinforcing fibers 20 can be provided in a polymer matrix 21, surrounded by a coating 12. Accordingly, the present invention includes the provision of reinforcing fibers in either the core of the guidewire or the plastic sheath surrounding the core. The reinforcing fibers may be of any suitable material, such as carbon, borium, aramide, or glass.

The guidewire of the present invention may also be constructed of more than one glass core body, all of which may be clad as a unit with a single protective coating.

It should be understood that an unlimited number of configurations for the present invention can be realized. The foregoing discussion describes merely exemplary embodiments illustrating the principles of the present invention, the scope of which is recited in the following claims. Those skilled in the art will readily recognize from the description, claims, and drawings that numerous changes and modifications can be made without departing from the spirit and scope of the invention.